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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,285	03/02/2005	Nitin Bhalachandra Dharmadhikari	006420.00004	4683

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EXAMINER	
GRAFFEO, MICHEL	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,285	DHARMADHIKARI ET AL.	
	Examiner	Art Unit	
	Michel Graffeo	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-18,23 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-18, 23 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Action

Claims 1, 3-18, 23 and 27 are examined.

Applicant has amended claims 1 and 3-6 cancelled claims 2, 19-22, 24-26 and 28 and provided arguments for the patentability of claims 1, 3-18, 23 and 27 in the response filed 13 December 2006. Examiner also acknowledges the amendment to the Specification.

Applicant's arguments, see response, filed 13 December 2006, have been fully considered and are persuasive to the extent of the rejections under 35 USC §112 and §102 have been withdrawn. Any rejection not specifically stated in this Office Action has been withdrawn.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 13 December 2006 has been entered.

New Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-18 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding the above claims, the Specification does not reasonably convey to one skilled in the art that the inventor(s) had possession of a pharmaceutical composition having enhanced oral bioavailability as compared to a composition "corresponding" to the claimed NDA. The word corresponding is open language in that it includes forms of metaxalone which are somehow related to or associated with tangentially the NDA. Language such as "described" in the NDA may be preferred.

Claim Rejections - 35 USC § 103

Claims 1, 3-15 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,407,128 to Scaife et al. in view of US Patent No. 6,030,988 to Gilis et al.

Scaife et al. teach a pharmaceutical composition comprising a 400mg tablet, inclusive of excipients, (see col 1 lines 28-29) of metaxalone (see Treatment A in col 3

lines 14-15) having an enhanced oral bioavailibility and necessary increased solubility in that it is dosed with food (see Title and Abstract).

Scaife et al. do not teach any particular values for the size of the metaxalone particles in the dosage form nor name any particular solubilizing agent such as monoglyceride for example.

Gilis et al. teach a micronized formulation of cisapride, inclusive of a solubilizing agent such as monoglycerides (see col 9 line 45) wherein at most 50% of the particles may have a diameter larger than 24 μm which allows for particle sizes of 40 μm, 30 μm and 10 μm (see col 5 lines 45-50) and a surface area per unit volume of more than $14x10^3$ m^2/kg, which when compared based on a 1cc=1g (for water) basis equates to an amount more than1400 m^2/kg and since the particle size ranges in the reference are the same as in the instant claims the ranges for the surface area unit volume must also be the same (see col 5 lines 39-45).

One of ordinary skill in the art would have been motivated to combine the above references and as combined would teach the invention as claimed. One of ordinary skill in the art would have been motivated to combine Scaife et al. with Gilis et al. since Scaife et al. cites Gilis et al. on the front page of the Scaife et al. patent. Further, Gilis et al. is directed to formulation with rapid dissolution and greater bioavailability (see for example Abstract of Gilis et al.). Thus, the combined references teach and make prima facie obvious how to use the claimed invention at the time that it was made.

Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,407,128 to Scaife et al. as applied to claims 1, 3-15 and 27 above in view of US Patent No. 6,099,859 to Cheng et al.

Scaife et al. do not teach a pharmaceutical comprising a wetting agent such as sodium lauryl sulfate.

Cheng et al. teach a pharmaceutical comprising sodium lauryl sulfate (see col 7 lines 35-40 in Example 2).

One of ordinary skill in the art would have been motivated to combine the above references and as combined would teach the invention as claimed. One of ordinary skill in the art would have been motivated to combine Scaife et al. with Cheng et al. since Scaife et al. cites Cheng et al. on the font page of the patent. Moreover, Cheng et al. further teach the increase of bioavailability of the composition when prepared by the method of Cheng et al. (see col 9 lines 40-52). Thus, the combined references teach and make prima facie obvious how to use the claimed invention at the time that it was made.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,407,128 to Scaife et al. as applied to claims 1, 3-15 and 27 above.

Although Scaife et al. do not particularly recite a pharmaceutical composition comprising metaxalone and another analgesic, combining agents which are known to be useful as aalgesics individually into a singe composition useful for the very same purpose is prima facie obvious. See In re Kerkhoven 205 USPQ 1069.

Since it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, the idea of combining analgesics flows logically from their having been individually taught in the prior art.

Response to Arguments - 35 USC § 103

Applicant's arguments filed 13 December 2006 have been fully considered but they are not persuasive. Applicant argues that one would be taught away from the notion of a form of metaxalone that is different from the conventional form because the Scaife et al. reference compares bioavailability of the conventional form when taken with or without food. This is not persuasive since there is nothing in the reference to teach away from another formulation and also because the rejection is over a combination of references which as combined teach the claimed formulation. To that extent the burden is on the Applicant to show that the bioavailability of the obvious formulation (that taught in the combination of references) is greater than that described in the NDA. Similarly, in response to Applicant's argument that micronization does not necessarily lead to increased bioavailability, it is up to Applicant to show that the mexatalone described in the combination of references has better bioavalibility. Even that Gilis et al. describe that sometimes a coarser material is needed (see Applicant's arguments page 16), a micronized embodiment as claimed is nonetheless taught.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by

combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Scaife et al. reference cites the Gilis et al. and Cheng et al. references. Moreover, the Gilis et al. reference is directed to formulation with rapid dissolution and greater bioavailability (see for example Abstract of Gilis et al.). Gilles et al. further teach a micronized formulation of cisapride which in light of the teachings above as a motivating factor to micronize a formulation for bioavailability makes obvious the instant claims. Additionally, that one reference is sited by another is a sufficient motivating factor to combine the references.

Applicant's argument that Gilis et al. do not claim a solubility improved salt form of metaxalone is not persuasive because Gilis et al. teach salts that are particular to cisapride. Gilis et al. teach that therapeutically effective salts should be use which is understood in the combination of references to include those salts which are therapeutically effective for metaxalone (see col 5 lines 5-10).

Applicants contend that the reliance on Cheng et al. is not proper. Cheng et al. is sited by Scaife et al. and therefore properly combined. Further, Cheng et al. teach a formulation comprising sodium lauryl sulfate as a surfactant. Sodium lauryl sulfate is a common surfactant used as a detergent, wetting agent, and food additive. (see sodium lauryl sulfate. Academic Press Dictionary of Science and Technology (1992). Retrieved

22 May 2006, from xreferplus. http://www.xreferplus.com/entry/3159939 and cited in prior Office Action). To that extent, one of ordinary skill in the art would have had in their possession all the limitations to the claimed invention and a proper motivation to combine all the limitations of the instant claims.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michel Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

12 March 2007
MG

Ardin H. Marschel 3/7/07

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER